

REMARKS

Claims 19-27 and 32-33 are currently pending in the present application, of which claims 19 and 32 are independent. Claims 1-11 were previously cancelled and claims 12-18, 28-31, and 34-26 have been withdrawn without prejudice. Claims 19-27 and 32-33 have been rejected.

35 U.S.C. §103(a)

Claims 19-27 and 32-33 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Parisi (U.S. Patent No. 4,861,332) (hereinafter, "Parisi") in view of Scheller, et al. (U.S. Patent No. 4,933,843) (hereinafter, "Scheller"), Tu (U.S. Patent No. 5,968,005) (hereinafter, "Tu"), and in further view of Broadwin, et al. (U.S. 4,827,911) (hereinafter, "Broadwin"). Applicant respectfully traverses this rejection for at least the following reasons.

35 U.S.C. §103(a) sets forth in part:

[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the difference between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said matter pertains.

To establish a *prima facie* case of obviousness the prior art reference (or references when combined) must teach or suggest all of the claim limitations. MPEP §2142; Verlander v. Garner, 248 F.3d 1359, 1363 (Fed. Cir. 2003).

The Examiner has failed to establish a *prima facie* case of obviousness and the currently pending claims are not rendered obvious in light of Parisi in view of Scheller, Tu, and Broadwin.

Applicant agrees with the Examiner assessment that Parisi "does not disclose a control console or an algorithm to control temperature in the area of application

within the body.” Office Action, p. 3. The Examiner asserts that “the teachings of Parisi emphasize the importance of temperature control, and moreover, the use of an irrigation system to control temperature at the distal tip of the handpiece to prevent damage to tissue.” Office Action, p. 3. However, Parisi is silent about controlling temperature at the distal tip of the handpiece to prevent tissue damage. In fact, Parisi fails to teach or suggest prevention of tissue damage at all. The Examiner cites col.6, line 61-col. 7, line 5, which is reproduced below.

In summary, the ultrasonic probe 10 of the present invention, having uniform and constant prestress compression loading of the piezoelectric transducer 18 and having parallel irrigation with the substantially straight-through aspiration through the operative tip 16, provides significant advantages over the prior art ultrasonic probes. The resilient compression coil spring 64 provides uniform compression loading which avoids breakage of the transducers during mounting, due to localized stresses, during mounting or operation of the transducers. Enhanced electromechanical coupling is also provided for improved operating efficiency at lower temperatures.

Based upon this section of Parisi, the Examiner draws an unsupported conclusion. In this section of Parisi, the discussion pertains to advantages over prior art probes including, uniform and constant prestress compression loading of the piezoelectric transducer 18 and having a parallel irrigation with substantially straight-through aspiration through the tip. The passage continues on to describe the resilient compression coil spring and its uniform compression loading; and the enhanced electromechanical coupling that improves operating efficiency at lower temperatures. The only discussion of temperature is Parisi’s discussion of the efficiency of the disclosed probe and operating the probe at lower overall temperatures. There is no discussion of the use of an irrigation system to control temperature at the distal tip of the handpiece.

Moreover, Parisi fails to teach or suggest a matrix comprising phaco power levels and fluid flow conditions that will not generate sufficient heat to create damage to eye tissue within the eye. Parisi teaches or suggest an improved probe with resilient uniform compression loading across a transducer assembly for

efficient, consistent and reliable operation, not balancing treatment parameters based on conditions occurring during a procedure. Scheller, Tu, and Broadwin fail to make up for the deficiencies of Parisi.

The Examiner acquiesces that Scheller “does not expressly disclose an algorithm to control the temperature at the distal tip of the handpiece using the irrigation and aspiration.” Office Action, p. 5. Further, Scheller fails to teach or suggest applying information gathered during a procedure to a matrix comprising phaco power levels and fluid flow conditions that will not generate sufficient heat to create damage to eye tissue within the eye.

The Examiner relies on Tu as disclosing “a temperature control algorithm.” Office Action, p. 5. However, Tu has nothing to do with phacoemulsification. The Examiner asserts that since Tu states, “[t]he RF energy delivery is controlled by the measured temperature and by a close-loop temperature control mechanism and/or algorithm” that it teaches the presently claimed invention. The Examiner is mistaken because Tu pertains to treating canker sores by heating therapeutic fluid and contacting the heated fluid with the canker sore for a period of time. Tu focuses on heating an electrode and a fluid, which is contrary to the present invention. Further, Tu fails to teach or suggest a matrix comprising phaco power levels and fluid flow conditions of claim 19 and further comprising power duty cycles of claim 32. At best, it teaches a temperature control mechanism, but nothing about power levels, fluid flow conditions, and power duty cycles, or the correlation between them such that the phacoemulsification system will not generate sufficient heat to create a burn of eye tissue. The mere mention of the term “algorithm” does not teach or suggest a matrix as claimed, especially since the features of the “algorithm” mentioned in Tu are not described.

The Examiner also cites Broadwin and specifically figures 1 and 2 as showing “an ultrasonic system for regulating fluid flow and energy into body tissue comprising of [a] handpiece, a control console, and most importantly, an algorithm

to maintain tissue temperature within a predetermined range.” Office Action, p. 6. The Examiner also cites particular sections of Broadwin to support his conclusion, namely col. 2, lines 3-17 and col. 6, line 56-col. 7, line 11. However, Broadwin and specific citations do not teach or suggest a matrix comprising phaco power levels and fluid flow conditions. The particular citations only describe controlling the duty cycle to control temperature. Thus, Broadwin fails to teach or suggest a matrix comprising phaco power levels and fluid flow conditions and fails to make up for the deficiencies of the other references.

Thus, the cited references fail to teach or suggest each and every element of the claimed invention and thus, fail to render the presently claimed invention obvious.

Combination of References

Assuming *arguendo* that the elements of the presently pending claims are taught or suggested by Parisi, Scheller, Tu, and Broadwin, the Examiner has not provided a sufficient reason for combining the references, except for a mere conclusion. The Examiner asserts that that “a person of ordinary skill in the art, modifying the apparatus disclosed by Parisi with a control console, as taught by Scheller, and furthermore, programming said control console to control the temperature at the distal tip of the handpiece, as taught by Tu and/or Broadwin, would have been considered obvious in view of the proven conventionality of these particular enhancements, and moreover, because such algorithm would have enhanced the accuracy of the overall system by preventing the destruction of good tissue by controlling the temperature in the area of application in the body.” Office Action, p. 7-8. The Examiner has not provided any evidence or support showing that the particular enhancements are conventional. Moreover, Applicant asserts that one of ordinary skill in the art would not have a reason to combine the references cited in the Office Action because Tu pertains to heating therapeutic fluid and contacting the fluid and electrode with a canker sore for treatment. Tu has nothing

to do with phacoemulsification or treating a cataract. Tu may mention ultrasonic energy, but a person of ordinary skill in the art would not look to a device for treating canker sores to solve a problem pertaining to phacoemulsification and cataracts. Further, Tu teaches heating a fluid for treating canker sores and the present invention pertains to avoiding damaging heat with a matrix comprising phaco power levels and fluid flow conditions that will not generate sufficient heat to create damage to eye tissue within the eye. Thus, one of ordinary skill in the art would not look to a treatment of mouth sores using heated fluid to solve a problem associated phacoemulsification and minimizing heat generated by a handpiece.

Applicant submits that a combination of these references is unreasonable, and such a combination is using hindsight to reconstruct the claimed invention. The PTO has the burden of establishing a *prima facie* case of obviousness under 35 USC §103. The Patent Office must show that there is some reason to combine the elements with some rational underpinning that would lead an individual of ordinary skill in the art to combine the relevant teachings of the references. KSR International Co. v. Teleflex Inc., No. 04-1350, 550 U.S. ____ (2007); In re Fine, 837 F.2d 1071, 1074 (Fed. Cir. 1988). Therefore, a combination of relevant teachings alone is insufficient grounds to establish obviousness, absent some reason for one of ordinary skill in the art to do so. Fine at 1075. In this case, the Examiner has not pointed to any cogent, supportable reason that would lead an artisan of ordinary skill in the art to come up with the claimed invention.

None of the references, alone or in combination, teach the unique features called for in the claims. It is impermissible hindsight reasoning to pick a feature here and there from among the references to construct a hypothetical combination which obviates the claims.

It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's

structure as a template and selecting elements from references to fill the gaps. [citation omitted]

In re Gordon, 18 USPQ.2d 1885, 1888 (Fed. Cir. 1991).

A large number of devices may exist in the prior art where, if the prior art be disregarded as to its content, purpose, mode of operation and general context, the several elements claimed by the Applicant, if taken individually, may be disclosed. However, the important thing to recognize is that the reason for combining these elements in any way to meet Applicant's claims only becomes obvious, if at all, when considered from hindsight in the light of the application disclosure. The Federal Circuit has stressed that the "decisionmaker must step backward in time and into the shoes worn by a person having ordinary skill in the art when the invention was unknown and just before it was made." Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1566 (Fed. Cir. 1987). To do otherwise would be to apply hindsight reconstruction, which has been strongly discouraged by the Federal Circuit. *Id.* at 1568.

To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

W.L. Gore & Assoc. v. Garlock, Inc., 721 F.2d 1540, 1553 (Fed. Cir. 1983). Therefore, without some reason in the references to combine the cited prior art teachings, with some rational underpinnings for such a reason, the Examiner's conclusory statement that an algorithm "to control the temperature at the distal tip of a handpiece using the irrigation and aspiration" is well known in the art to support of the alleged combination fails to establish a *prima facie* case for obviousness. *See*, KSR International Co. v. Teleflex Inc., No. 04-1350, 550 U.S. ____ (2007)

(obviousness determination requires looking at “whether there was an apparent reason to combine the known elements in the fashion claimed...,” citing In re Kahn, 441 F.3d 977, 988 (CA Fed. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness,” KSR at 14).

Based upon the totality of the foregoing, Applicant respectfully submits that claims 19 and 32, are allowable over the references of record, as well as the claims that depend therefrom.

Accordingly, it is respectfully submitted that all pending claims fully comply with 35 U.S.C. § 103.

CONCLUSION


It is respectfully submitted that all claims of the present application are in condition for allowance. Consideration and allowance of all pending claims at an early date is respectfully requested.

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Should any additional fees be due, the Commissioner is hereby authorized to charge any deficiencies or credit any overpayment to Deposit Account No. 502317. Should the Examiner have any questions or concerns, please do not hesitate to contact the undersigning attorney at 714-247-8422.

Respectfully submitted,

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